PATENT
Attorney Docket No. 102.0001-12000
Customer No. 22882
Express Mail No. ET692326444US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of: | ) | |
| Gary K. Michelson, M.D. | ) | Group Art Unit: (3764) |
| Serial No.: (Cont. of 10/685,776) | ) | |
| Filed: December 19, 2003 | ) | Examiner: (M. Brown) |
| For: SPINAL IMPLANT FOR INSERTION BETWEEN VERTEBRAL BODIES | ) | |

Mail Stop PATENT APPLICATION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicant brings to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed concurrently with the above-referenced application.

Copies of the listed documents were previously cited in a prior application, Serial No. 10/685,776, filed October 15, 2003, and/or Serial No. 08/480,684, filed June 7, 1995, upon which applicant relies for the benefits provided in 35 U.S.C. § 120.

Please note that ES 283078 is related to U.S. Patent No. 4,877,020; EP 0268115 is related to U.S. Patent No. 4,820,305; DE 26 21 384 is related to U.S. Patent No. 4,177,524; and GB 1291470 is related to DE 1961531.

The present application is a continuation application of Serial No. 10/685,776, filed October 15, 2003, which is a continuation application of Serial No. 08/480,684, filed June 7, 1995. The '684 application is a divisional application of Serial No.

07/968,240, now U.S. Patent No. 5,741,253, which is a continuation of application Serial No. 07/698,674, now abandoned, which is a divisional application of Serial No. 07/205,935, now U.S. Patent No. 5,015,247.

Applicant brings to the Examiner's attention that the '247 patent was the subject of litigation in the United States District Court for the Central District of California, Western Division, Civil Action No. 95-0258RG, hereinafter referred to as Litigation 1. The claims of the '247 patent are directed to a fusion implant.

The '253 patent was the subject of litigation in the United States District Court for the Western District of Tennessee, Civil Action No. 98-2369GA (JSG), hereinafter referred to as Litigation 2. The '253 patent was also the subject of litigation in the United States District Court for the Western District of Tennessee, Western Division, Case No. 99-2656GV, hereinafter referred to as Litigation 3 ("Lit. 3"). The claims of the '253 patent are generally directed to a method for preparing adjacent vertebrae to receive an implant.

U.S. Patent No. 5,484,437 (a continuation in part of the '253 patent) and U.S. Patent No. 6,096,038 (a divisional of the '437 patent) were also the subject of litigation in Litigation 3. The claims of the '437 patent are generally directed to a method for inserting an implant. The claims of the '038 patent are generally directed to instruments used for preparing adjacent vertebrae to receive an implant and/or inserting an implant.

In Litigations 1-3, the defendants asserted that various references were pertinent to the issue of validity of the '247 patent, the '253 patent, the '437 patent, and the '038 patent under 35 U.S.C. §§ 102 and 103. Applicant notes for the Examiner on the attached Form PTO-1449 in the column for the Examiner's initials the references

identified by defendants in Litigation 1 as being allegedly pertinent to the '247 patent by the designation "Lit. 1." References identified by the defendants in Litigation 2 as being allegedly pertinent to the '253 patent are identified by the designation "Lit. 2." References identified by the defendants in Litigation 3 as being allegedly pertinent to the '437 patent are identified by the designation "Lit. 3a." References identified by defendants in Litigation 3 as being allegedly pertinent to the '253 patent are identified by the designation "Lit. 3b." References identified by defendants in Litigation 3 as being allegedly pertinent to the '038 patent are identified by the designation "Lit. 3c."

The defendants in Litigation 3 also raised allegations of inequitable conduct in relation to the procurement of:

(1) the '253 patent for failing to (a) highlight U.S. Patent No. 4,570,624 to Wu, (b) disclose litigation related to the '247 patent, and (c) disclose EP 0077159 to Atkins, an article written by Jose Vich ("Anterior cervical interbody fusion with threaded cylindrical bone," *Neurosurg* 63: 750-753, 1985), and manuals by Muller, M.E. ("Manual of Internal Fixation: Techniques Recommended by the AO Group;" Second Edition, Expanded and Revised; pp. 3-20, 27-41, 53-58, 71-78, 94, 311, 320; Springer-Verlag; 1979), Hierholzer, G. ("Manual on the AO/ASIF Tubular External Fixator;" pp. 85-91; Springer-Verlag; 1985), and Heim, Urs ("Small Fragment Set Manual: Technique Recommended by the ASIF-Group;" pp. 5-7, 10, 20, 21, 30; Springer-Verlag; 1974);

(2) the '437 patent for failing to (a) disclose the existence of and information surrounding litigation concerning inventorship issues with the subject matter of U.S. Patent No. 5,489,307 to Kuslich and (b) disclose U.S. Patent No. 2,842,131 to Smith, U.S. Patent No. 4,142,517 to Stavropoulos et al., U.S. Patent No. 4,677,883 to Lee,

U.S. Patent No. 4,830,000 to Shutt, U.S. Patent No. 4,878,915 to Brantigan, U.S. Patent No. 4,943,291 to Tanguy, U.S. Patent No. 4,961,740 to Ray et al., and U.S. Patent No. 5,055,104 to Ray; and

(3) the '038 patent for failing to (a) disclose the existence of and information surrounding litigation concerning inventorship issues with the subject matter of U.S. Patent No. 5,489,307 to Kuslich and (b) filing an allegedly misleading Rule 131 declaration.

Litigations 1-3 are no longer pending. The jury in Litigation 2 found all asserted claims of the '253 patent valid in view of the art cited by the defendant. Litigations 1-3 were settled with the defendants in each litigation retracting their assertions of invalidity and inequitable conduct. Discovery documents relating to the aforementioned litigations are available upon request.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicant determines that the cited documents do not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 50-1068.

Respectfully submitted,

MARTIN & FERRARO, LLP

Date: December 19, 2003

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OMB 0651-0031
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| Substitute for FORM PTO-1449 | Attorney Docket Number 102.0001-12000 | Customer No. 22882 | |
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| **INFORMATION DISCLOSURE CITATION IN AN APPLICATION** | Applicant Gary K. Michelson, M.D. | Application Number (Cont. of 10/685,776) | |
| *(Use several sheets if necessary)* Sheet 1 of 4 | Filing Date December 19, 2003 | Group Art Unit (3764) | Examiner (M. Brown) |

## U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|---|---|---|---|---|---|---|
| | D 257511 | Nov-80 | Zahn | | | |
| | D 260525 | Sep-81 | Lassiter | | | |
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| Lit. 2 | 3,128,768 | Apr-64 | Geistauts | | | |
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| | 3,426,364 | Feb-69 | Lumb | | | |
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| **EXAMINER** | **DATE CONSIDERED** |
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.